Guidance Document for Completing the Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States

Please review this guidance document in its entirety before completing and submitting your application to the CDC Etiologic Agent Import Permit Program (EAIPP). If you are faxing or emailing your application, *there is no need to send in the original by mail*.

IMPORTANT NOTE: If the material being imported has been rendered sterile (e.g., thermal, chemical, or irradiation treatment) or it has been confirmed not to contain infectious agents for humans, then a CDC issued import permit is not required for importation. Examples of material that *does not* require a CDC issued import permit include:

- **Non-infectious materials**, e.g., formalin-fixed specimens, tissues, or slides, or non-infectious human stem cells or non-infectious human organs for transplantation.
- **Human or animal diagnostic specimens** such as blood, urine, and tissues in which there is no evidence or indication that such material contain an infectious agent. Note that specimens from humans may be subject to the Bloodborne Pathogens Standard (29 C.F.R. 1910.1030) and that specimens from animals may require a permit from USDA's Animal and Plant Health Inspection Service (APHIS). Information concerning APHIS permitting may be found at http://www.aphis.usda.gov/permits.
- **Laboratory mice, rats, and hamsters** reared under specific pathogen-free (SPF) conditions. In addition, genetically altered animals (e.g., "knockout" or "transgenic") do not require a CDC import permit provided that the animals contain no pathogens known to be transmissible to humans. NOTE: If the rodents are to be imported from Africa or are species of African origin, they may only be imported for scientific, education, or exhibition purposes with permission granted from CDC's Division of Global Migration and Quarantine. Information regarding DGMQ is available at: http://www.cdc.gov/ncpdcid/dgmq/index.html.
- **Fully-taxidermied or treated non-human primates trophies, skins, or skulls**, any non-human primate trophies, skins or skulls that have been either fully taxidermied or treated to render them non-infectious may be imported without a CDC import permit.

U.S. Customs and Border Protection (CBP) may require documentation that the material being imported is not infectious to humans. CDC advises that importers of materials that do not require a CDC import permit include a signed statement, on their official letterhead, from the person responsible for the shipment of the material with the following information:

(a) A description of the material;

(b) A statement that the material meets one of the above criteria (e.g., human urine diagnostic specimens in which there is no evidence that such material contain an etiologic agent); and

(c) Verification that the material has been packaged, labeled, and transported in accordance with all applicable regulations.

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Section A - Person Requesting Permit in U.S.A. (Permittee)

Since all communication with the CDC Etiologic Agent Import Permit Program (EAIPP) is completed through the Permittee, it is imperative that the Permittee contact information be complete, current and accurate. If any of the *Section A* information changes, you must immediately report the change(s) to the Program by submitting a new Import Permit application amending the current contact information (i.e., fax or phone number). The EAIPP does not accept verbal change requests.

Blocks 1-3, Permittee's Name

- Please provide the full name of the applicant.
  - For the purposes of completing the Application for Permit to Import Biological Agents or Vectors into the United States, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Block 4, Permittee's Organization

- Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Blocks 5-8, Physical Address

- Please provide the complete business address of the individual listed in *Blocks 1-3*.
- Do not use a Post Office Box address.

Block 9, Telephone Number

- Please provide the direct dial 10-digit telephone number for the Permittee listed in *Blocks 1-3*; include an extension, if required.

Block 10, Fax Number

- Please provide the 10-digit facsimile number for the Permittee listed in *Blocks 1-3*.

Block 11, E-mail Address

- Please provide the e-mail address for the Permittee listed in *Blocks 1-3*.
- Please print or type clearly; and ensure that you include the e-mail domain (e.g., .org, .gov, .edu, .com, .net)

Block 12, Courier Method

- If the Permittee listed in Blocks 1-3 intends to hand-carry the biological agent(s) or vector(s) to be imported, check "Yes."
- If the biological agent(s) or vector(s) will be imported using a commercial carrier, check "No."

Block 13, Other Authorized Individuals

- If there are other members of your organization who will be authorized to use the approved permit select "Yes", check the box in *Block 14*, and list all additional authorized users on the CDC Form 0.753. A continuation form is available at http://www.cdc.gov/od/eaipp/importApplicationForms.htm.
  - Please include all required information (*Blocks 1-11*) for each additional authorized user.
  - Please note that each individual import permit can have a maximum of 10 additional authorized users.
- Otherwise, select "No."

Section B - Sender of Imported Biological Agent(s)

The CDC Import Permit is for material being imported into the United States (U.S.). United States means the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

Blocks 1-3, Sender's Name

- Please provide the full name of the sender.
  - For the purposes of completing the application for Permit to Import Biological Agents or Vectors of Human Disease, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
- If the sender is also the person requesting the permit, please check the box labeled "Check if same as Sec A" and complete *Blocks 4-12* with the information from the international address from which the material will be shipped.

Block 4, Sender's Organization

- Please provide the complete name of the entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Blocks 5-7, Physical Address

- Please provide the complete address of the entity.
- Do not use a Post Office Box address.

Block 8, Country

- Please provide the unabbreviated country name.

Block 9, Postal Code

- Please provide the complete Postal Code.

Block 10, Telephone Number

- Please provide the direct dial telephone number for the sender listed in *Section B, Block 1*; include the appropriate international prefixes and an extension, if appropriate.

Block 11, Fax Number

- Please provide the facsimile number for the sender listed in *Section B, Blocks 1-3,* if known.

Block 12, E-mail Address

- Please provide the e-mail address for the sender listed in *Section B, Block 1,* if known.
- Please print or type clearly and ensure that you include the e-mail domain (e.g., .org, .gov, .edu, .com, .net)

Block 13, Additional Senders

- If the biological agent(s) or vector(s) are coming from more than one sender, please check the box in *Block 13* and list all additional senders on the CDC Form 0.753 EAIPP Continuation form available at http://www.cdc.gov/od/eaipp/importApplicationForms.htm.
    - Please include all required information (*Blocks 1-12*) for each additional sender.

Section C, Shipment Information

Block 1, Method of Shipment

- Please select the method of shipment.
    - **Commercial Carrier**, select if the biological agent(s) or vector(s) to be imported will be transported using a common commercial carrier such as FedEx or World Courier.
    - **Hand-carried**, select if the biological agent(s) or vector(s) to be imported will be transported into the United States under the control of an individual authorized under the issued permit.

Block 2, Number of Shipments

- Please select “single” or “multiple” shipments.
    - **Single shipment**, select if one shipment of material will be imported into the U.S. under the issued permit.
    - **Multiple shipments**, select if more than one shipment of material imported into the U.S. is anticipated. For multiple importations, check box and indicate the number of estimated shipments.

Block 3, Shipment Temperature

- Please select the shipment temperature(s) required for the biological agent(s).
    - **Ambient**, shipped under surrounding temperature conditions (i.e., no temperature control/regulation).
    - **Frozen/Refrigerated**, shipped under refrigerated or frozen conditions (i.e., wet ice, dry ice, cold packs).

Block 4, Anticipated U.S. Port(s) of Entry

- List the port(s) of entry where the biological agent(s) or vector(s) are expected to enter into the U.S.
    - A "U.S. Port of Entry" means one of the 327 official ports of entry in the U.S. at which U.S. Customs and Border Protection (CBP) enforces the import and export laws and regulations of the U.S. federal government and conducts immigration policy and programs. Ports also perform agriculture inspections to protect the USA from potential carriers of animal and plant pests or diseases that could cause serious damage to America's crops, livestock, pets, and the environment. Further information is available at http://www.cbp.gov/xp/cgov/toolbox/contacts/ports/.

Section D- Final Destination of Imported Biological Agent

Complete this section only if the final destination differs from the address listed in Section A.

Block 1, Final Destination Address

- If the final destination of the biological agents is the address listed in Section A select "No" and do not complete *Blocks 2-12* of Section D. Continue to Section E.
- Otherwise select "Yes" and complete *Blocks 2-12*.

Blocks 2-4, Name of Recipient at Destination

- Please provide the full name of the Recipient.
    - For the purposes of completing the application for Permit to Import or Transport Biological Agents or Vectors of Human Disease, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Block 5, Destination Organization

- Please provide the complete name of the entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Blocks 6-9, Final Destination Address

- Please provide the complete address for the final destination of the imported biological agent(s) or vector(s).
- Do not use a Post Office Box address.

Block 10, Telephone Number

- Please provide the direct dial 10-digit telephone number for the recipient listed in *Blocks 2-4* of Section D; include an extension, if required.

Block 11, FAX Number

- Please provide the 10-digit facsimile machine number for the individual listed in *Blocks 2-4* of Section D.

Block 12, E-mail Address

- Please provide the e-mail address for the recipient listed in *Blocks 2-4* of *Section D*.
- Please print or type clearly; and ensure that you include the e-mail domain (e.g., .org, .gov, .edu, .com, .net)

Block 13, Additional Final Destinations

- If the biological agent(s) or vector(s) will be transferred to more than one final destination, please check the box in *Block 13* and list all additional final destinations on the CDC Form 0.753 Continuation form available at http://www.cdc.gov/od/eaipp/importApplicationForms.htm.
  - Please include all required information (*Blocks 1-11* of Section D) for each final destination.

Section E- Description of Imported Biological Agent(s)

This section should contain the information describing the biological agent(s) to be imported and the intended use of the agent(s). Any incomplete or illegible entries will result in delay or denial of your application. If the biological agent(s) being imported has been rendered sterile (e.g., thermal, chemical, or irradiation treatment) or has been confirmed not to contain infectious agents for humans, then a permit is not required for importation.

Block 1, Intended Use(s) of Imported Agent

- When completing *Block 1*, please refer to the definitions listed below for indicating the intended use(s) of the agent being imported:
  - **Diagnostic:** Clinical/laboratory testing to identify a particular biological agent, disease, and/or characteristic of the agent/disease.
  - **Research:** Basic or applied scientific investigation and/or experimentation following a defined protocol and other standards for research projects that is intended to advance scientific knowledge and/or to explore scientific theories/hypotheses.
  - **Clinical trials:** Controlled studies to evaluate the effects, safety, and efficacy of a drug, vaccine, medical device, or therapy protocol.
  - **Education:** Teaching of a defined educational program or part of an educational display by a non-profit, commercial, or sole proprietor institution.
  - **Production:** Activities related to the processing of the imported biological agent(s) as a raw material into semi finished or finished goods.
  - **Other:** Any other previously undefined proposed use of the material/biological agent(s) that does not fall under one of the five types listed above. If "Other" is selected, please provide a detailed description.

Block 2, Detailed Description of Work Objectives

- Please clearly and thoroughly describe the objectives of the work intended for the biological agents being imported (e.g., pharmaceutical/clinical trials testing, susceptibility testing, recombinant DNA work, etc.)

- Also, include information regarding the background, purpose, and methods of your intended work with the imported biological agent(s).
    - *Example:* We intend to test the susceptibility of *Staphylococcus aureus* as part of a new clinical trial using drug susceptibility plating and PCR testing.

Block 3, Scientific Name of Known/Suspected Biological Agent(s)

- Please list the complete (unabbreviated) taxonomic genus and species names or the common name of for the known/suspected biological agent(s) to be imported.
    - *Examples*: *Plasmodium falciparum*, *Escherichia coli*, Human Immunodeficiency Virus
- Please do not list the disease. (For example: Do not list "Cholera", list "*Vibrio cholera*.")

Block 4, Type of Biological Agent

- Select the type of biological agent being imported for each agent listed in *Block 3*.
- When completing *Block 4*, please refer to the definitions and examples listed below for indicating the types of biological agent being imported:
    - **Bacteria:** Single-celled microorganisms which can exist either as independent (free-living) organisms or as parasites (dependent upon another organism for life).
        - *Examples: Escherichia coli, Salmonella typhi, Staphylococcus aureus*
    - **Virus:** A microorganism smaller than a bacterium, which cannot grow or reproduce apart from a living cell.
        - *Examples:* Human Immunodeficiency Virus (HIV), cytomegalovirus, varicella zoster virus
    - **Fungi:** Large group of plant-like living organisms which do not contain chlorophyll.
        - *Examples:* Yeasts, molds and mushrooms
    - **Toxin:** Poisonous products of organisms that are inanimate and not capable of reproducing themselves.
        - *Examples:* Diphtheria toxin, Modeccin, Pneumolysin
    - **Parasite:** An organism that grows, feeds, and is sheltered on, or in a different organism while contributing nothing to the survival of its host.
        - *Examples: Dirofilaria immitis, Giardia lamblia, Plasmodium falciparum*
    - **Prion:** A microscopic protein particle similar to a virus but lacking nucleic acid.
        - *Examples:* Prion diseases include Creutzfeldt-Jakob disease (CJD), kuru, bovine spongiform encephalopathy (BSE), scrapie
    - **Recombinant Genetic Material:** Recombinant DNA/RNA are molecules constructed outside of living cells by joining natural or synthetic DNA/RNA segments to DNA/RNA molecules that can replicate in a living cell, or molecules that result from their replication.

Block 5, Additional Biological Agents

- If more than four biological agents will be imported, please list all additional biological agents using the CDC Form 0.753 Continuation form available at http://www.cdc.gov/od/eaipp/importApplicationForms.htm.
  - Please include all the required information (*Blocks 3-4*) for each biological agent.

Section F- Description of Material Containing the Biological Agent(s) to be Imported

This section should contain the information describing the material or vector(s) containing the biological agent(s) to be imported and its origins. Any incomplete or illegible entries may result in delay or denial of your application. If the biological agent(s) contained in the material or vector(s) being imported has been rendered sterile (e.g., radiation or chemical treatment) or has been confirmed not to contain infectious agents for humans, then a permit is not required for importation.

Block 1, Source of Material Being Imported

- When completing *Block 1*, please refer to the definitions listed below for indicating the source of the material being imported:
  - **Infected or suspected infected human:** Material collected/obtained from a living or deceased human being that is known or suspected to contain one or more disease-causing biological agents
    - *Examples*: Infected sputum sample known to contain *Mycobacterium tuberculosis*.
  - **Infected or suspected infected vector:** Material collected/obtained from a living or deceased animal (including insects) or thing which conveys or is capable of conveying biological agents from a person or animal to another person or animal that is known or suspected to contain one or more disease-causing biological agents.
    - *Examples*: Culex mosquitoes (*Culex quinquefasciatus*) known to contain West Nile Virus.
  - **Environment:** Material collected/obtained from natural surroundings that are known or suspected to contain one or more disease-causing biological agents.
    - *Examples*: Soil, ground/surface water, sediment, effluent suspected to contain a biological organism capable of causing disease in humans.
  - **Other:** Any other previously undefined material source that does not fall under one of the four types listed above. If "Other" is selected, please provide a detailed description.

Block 2, Description of Material Containing Biological Agent

- When completing *Block 2*, please refer to the definitions listed below for indicating the description of the material containing the biological agent being imported:
  - **Field-collected specimen:** Infectious material or specimens gathered in a natural setting other than research facility, laboratory, hospital, etc.

        - *Examples*: Soil sample suspected to contain a biological organism capable of causing disease in humans.
    - **Laboratory Isolate/culture:** Biological agent streaked onto or placed in a medium to obtain an independent isolate or purified culture that contains a microorganism.
        - *Examples*: Agar plate containing bacterial growth
    - **Blood/Blood products:** Whole blood or the constituents of whole blood such as plasma or platelets.
        - *Examples*: Blood sample drawn from infected patient
    - **Other Body Fluids:** A natural bodily fluid or secretion of fluid such as lymph, urine or saliva.
        - *Examples*: Sputum sample from infected patient
    - **Tissues/organs:** Unsterilized material of animal or human origin known or suspected of containing a biological organism capable of causing disease in humans.
        - *Examples*: Muscle tissue, lung, skin biopsy suspected of containing a biological organism capable of causing disease in humans.
    - **Body parts:** Unsterilized specimens of animal or human origin known or suspected of containing a biological organism capable of causing disease in humans.
        - *Examples*: head, arm suspected of containing a biological organism capable of causing disease in humans.
    - **Vector:** A carrier, especially the animal (usually an arthropod) that transfers an infective agent from one host to another.
        - *Examples*: Mosquitoes suspected of containing a biological organism capable of causing disease in humans.
    - **Other:** Anything containing infectious material or microorganisms capable of causing disease, and/or death or other biological malfunction in humans.
        - *Examples*: Compost, cell lines, biosolids
- Please include a detailed written description of the material being imported.

Block 3, Fetal Calf Serum or Bovine Serum Albumin

- If the material contains any amount of fetal calf serum or bovine serum albumin, please select “Yes”, otherwise select “No”
    - Please be reminded that any material containing fetal calf serum or bovine serum albumin may require a permit from the U.S. Department of Agriculture, http://www.aphis.usda.gov/permits/.

Section G- Receiving Laboratory Capabilities

This section should contain the information describing the receiving laboratory's capabilities and protocols. Any incomplete or illegible entries will result in delay or denial of your application.

Block 1, Laboratory Biosafety Level

- Please indicate the biosafety level of the laboratory(s) where the work with the imported agent(s) will occur. Definitions of laboratory biosafety levels are published in the *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* (BMBL). The current version of the BMBL is available at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm.

Block 2, Primary Containment to be Used

- Please select the primary containment measure(s) to be used for working safely with the imported agent(s). Refer to the table listed below and the *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* (BMBL) for more information on the types of biosafety cabinets and fume hoods at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf.
    - For any biological agent that will require the use of a high-containment facility (ABSL-3/BSL-3 or ABSL-4/BSL-4) or that poses an aerosol risk, please provide a detailed, written description of the primary containment measures to be used.
    - If the information provided is inadequate or incomplete, you may be asked to provide additional information regarding the primary containment measure(s) utilized at your facility.

Biological Risk Assessed	Protection Provided			BSC Class
	Personnel	Product	Environmental	
BSL 1, 3	Yes	No	Yes	I
BSL 1, 3	Yes	Yes	Yes	II (A1, A2, B1, B2)
BSL 4	Yes	Yes	Yes	III; II–When used in suit room with suit

Source: *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* (BMBL)

Block 3, Personal Protective Measures to be Used

- Please select the personal protective measure(s) to be used for working safely with the imported agent(s).
    - For any biological agent that will require the use of a high-containment facility (ABSL-3/BSL-3 or ABSL-4/BSL-4) or that poses an aerosol risk, please provide a detailed, written description of the personnel protective measures to be used.
    - If the information provided is inadequate or incomplete, you may be asked to provide additional information regarding the personal protective measure(s) utilized at your facility.

Block 4, Personnel Training Provided

- When completing *Block 4*, please refer to the statements listed below for indicating the personnel training provided to the individuals that will be handling the imported agent(s). *Please check all that apply*.

- **Risk(s) associated with the imported biological agent(s):** Personnel have received training regarding the hazardous characteristics of the known or suspected biological agents or material, the activities that can result in a person's exposure to the known/suspected agents, the likelihood that such an exposure will cause a Laboratory Acquired Infection (LAI), and the probable consequences of such an infection.
- **Hazardous Material Packing/Shipping:** Personnel have received training on how to correctly package, mark, label, and document hazardous biological material shipments according to U.S. Department of Transportation regulations and guidelines provided by the International Air Transport Association.
- **Laboratory Standard Practices:** Personnel have received training on how to safely handle, manipulate, and store the imported biological agent(s) to control the hazards associated with the agent(s) and to prevent direct and/or indirect exposure to the agent (e.g. agent and/or procedure specific Standard Operating Procedures, operation of containment/safety equipment, correct use of personal protective equipment, facility safeguards).
- **Hazardous Waste Handling/Disposal:** Personnel have received training on the principles of and procedures for biological agent decontamination, sterilization, disinfection, waste handling, and waste disposal specific to the imported agent(s) to prevent injury, minimize personal and environmental health hazards, and to meet regulatory requirements.
- **Emergency Response Procedures:** Personnel have received training on the appropriate response procedures that are specific for the hazards associated with the imported biological agent(s) and the necessary actions to contain the agent(s) in the event of an incident. Training should address response procedures for severe weather/natural disasters, workplace violence, bomb threats, suspicious packages, fire, gas leak, explosion, flood, power outage, etc.
- **Spill Procedures:** Personnel have received training on the appropriate spill response and clean-up procedures based upon the physical characteristics and volume of the agent(s)/materials being handled, their infective potential, the damage potential for releases to the environment, and the location of the spill.
- **Other:** Any other personnel training provided that does not fall under one of the six categories listed above. If "Other" is selected, please provide a detailed description.

- Personnel *curriculum vitaes* and/or lists of publications may also be requested.

Block 5, Anticipated disposition of Biological Agent (and material containing it) when work is completed

- When completing *Block 5*, please refer to the definitions listed below for indicating the final disposition of the material being imported:
  - **Retained:** Retaining material onsite for an extended period of time (e.g. greater than 30 days or retaining material after completion of the project for which it was used).
  - **Transferred:** Relocation of material to another facility. This address must be listed in *Section D*.

- **Destroyed:** Indicate the method of destruction by checking the appropriate box in *Block 6*.

Block 6, Method of Destruction

- When completing *Block 6*, please refer to the definitions listed below for indicating the method of destruction of the agent(s) being imported:
  - **Thermal**: Exposure of the agent to dry heat, moist heat (e.g., autoclave), or incineration at an appropriate temperature, pressure, and time to destroy or inactivate all of the specific biological agent.
  - **Chemical:** Exposure of the agent to a proven chemical at an appropriate concentration and for the appropriate exposure time to destroy or inactivate all of the specific biological agent.
  - **Irradiation:** Exposure of the agent to radiation of an appropriate type and for the appropriate exposure time to destroy or inactivate all of the specific biological agent.
  - **Other:** If "Other" is selected you must provide a detailed description of the destruction method.

Section H, Signature of Permittee (Mandatory Requirement)

IMPORTANT NOTE: By signing and submitting the completed *Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States* to the CDC Etiologic Agents Import Permit Program, the requestor (permittee) is certifying that all individuals listed in the application have the appropriate qualifications, experience and training to safely handle the agents being imported and that the information submitted in the application is complete and accurate to the best their knowledge and belief. They are also agreeing to comply with all conditions, restrictions, and precautions that may be specified in any permit that may be issued. Additionally, the requestor is agreeing to comply with all applicable regulations and guidelines that govern the importation and acknowledging that failure to comply with the importation requirements may subject them to criminal penalties pursuant to *42 U.S.C. 271*. The requestor is also acknowledging that any false statement made in the signed/submitted application may subject them to criminal penalties pursuant to *18 U.S.C. 1001*.

Block 1, Signature (REQUIRED)

- The Requestor listed in *Section A*, *Blocks 1-3*, must sign in *Section H*, *Block 1*.

Block 2, Requestor (Permittee)

- Please type or print the Requestor's name as it appears in *Section A*, *Block 1-3*.

Block 3, Date Signed

- Please enter the date the Requestor signs the application.

Document Change History

Version	Date	Summary of Changes
1.0	February 2011	Initial Release
1.1	March 2011	Updated Other Authorized Users and Method of Shipment